Louis H. Weinstein (LW 7868)
Andrew J. Miller (AM 8160)
BUDD LARNER, P.C.
150 John F. Kennedy Parkway
Short Hills, New Jersey 07078
(973) 379-4800
Attorneys for Defendants and
Counterclaim Plaintiffs
Dr. Reddy's Laboratories, Ltd. and
Dr. Reddy's Laboratories, Inc.

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE and ASTRAZENECA LP, KBI INC. and KBI-E, INC.,	07-CV-6790 (CM)(GWG)
Plaintiffs and Counterclaim Defendants,	
v.	**ELECTRONICALLY FILED**
DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC.	**(CONTAINS CONFIDENTIAL ASTRA INFORMATION)**
Defendants and Counterclaim Plaintiffs.	

DRL DEFENDANTS' REPLY
IN SUPPORT OF DRL'S MOTION FOR SUMMARY JUDGMENT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page

Cases

Rules

INDEX OF DECLARATIONS AND EXHIBITS
Submitted With DRL's Reply in Support of DRL's Motion for Summary Judgment

- Third Declaration of Louis H. Weinstein (Filed in Support of DRL's Motion for Summary Judgment) with following attached Exhibits:

  19. Documents submitted by DRL to the FDA in ANDA No. 78-878 (DRL0001 to DRL02971; DRL03855 to DRL03871)

  20. Documents submitted by DRL to the FDA in DMF No. 17706 (DRL02972 to DRL03854)

  21. Declaration of Per Lindberg from the prosecution history of U.S. Patent Application Serial No. 08/313,342

  22. Office Action Summary dated January 27, 1998 from the prosecution history of U.S. Patent Application Serial No. 08/313,342

  23. Amendment dated July 31, 1998 from the prosecution history of U.S. Patent Application Serial No. 08/313,342

  24. Marked up original claims from the prosecution history of U.S. Patent Application Serial No. 08/313,342

  25. Astra's November 19, 2007 Document Requests

  26. May 6, 2008 letter of Louis H. Weinstein, Esq. to Errol Taylor, Esq.

  27. May 7, 2008 letter of John Griem, Esq. to Louis H. Weinstein, Esq. with proposed Protective Order

  28. May 8, 2008 letter of Louis H. Weinstein to Magistrate Judge Maas

  29. May 9, 2008 letter of John M. Griem, Esq. to Magistrate Judge Maas

  30. May 13, 2008 e-mail from John M. Griem, Esq. to Louis H. Weinstein, Esq.

  31. May 16, 2008 e-mail from John M. Griem, Esq. to Louis H. Weinstein, Esq.

  32. May 20, 2008 e-mail from Louis H. Weinstein, Esq. to John M. Griem, Esq.

- Third Declaration of Harry G. Brittain, Ph.D., FRSC (Filed in Support of DRL's Motion for Summary Judgment)

- Declaration of Kumara Sekar, Ph.D. in Support of Dr. Reddy's Laboratories, Ltd.'s and Dr. Reddy's Laboratories, Inc.'s Motion for Summary Judgment

I. Astra's Belated Request for More Discovery Should Not Delay Summary Judgment

This case is ripe for summary judgment. Even Astra's expert does not say that DRL infringes a single claim. Luk Decl. ¶ 3.E. Dr. Luk's failure to opine that DRL infringes confirms DRL's long-asserted position that Astra lacks the evidence to shoulder its burden of proving infringement at trial. Unable to oppose summary judgment on the merits, Astra asks for a continuance so it can continue to search for a way to prove its case. But Astra already had what was effectively Rule 56(f) discovery -- and the Court ruled it would proceed to decide DRL's motion. The Court should now grant DRL summary judgment of non-infringement.

At the September 21, 2007 Conference "the Court stated that AstraZeneca should assume that DRL had made a motion for summary judgment." Griem Aff. ¶ 20. When Astra asked for discovery, the Court ordered DRL to produce samples and answer 10 Interrogatories, which it did. On November 7, Astra reported that its tests did not show infringement and sought more discovery. The Court told Astra to explain the infringement discovery it wanted and "to justify any additional discovery on a claim by claim basis." DRL Ex. 14 ¶ 1.[1] Astra did "nothing of the kind" and, ruling on Astra's first request for Rule 56(f) type discovery, the Court stated: "Astra-Zeneca's discovery requests smack of a fishing expedition." *Id.* ¶ 2 (emphasis added). Nevertheless, the Court ordered, and DRL produced, the requested portions of its ANDA and DMF and a witness with knowledge of DRL's process. Accordingly, the Court should disregard Astra's current Rule 56(f) Affidavit because the Court already gave Astra its opportunity to take Rule 56(f) discovery.

Metropolitan Life Ins. Co. v. Bancorp Services, L.L.C., 527 F.3d 1330 (Fed. Cir. 2008), on which Astra relies, is readily distinguishable. That patentee had not been given an "adequate

---

[1] "DRL Ex. __" refers to the Exhibits to the 2nd Weinstein Declaration (DRL Exhibits 1-18) and the Exhibits to the 3rd Weinstein Declaration (DRL Exhibits 19-32).

initial opportunity for discovery." *Id.* at 1337. In contrast, Astra received detailed interrogatory answers, samples, the relevant portions of DRL's ANDA and DMF and the deposition of a person with knowledge of DRL's process. Astra was also given the opportunity to obtain additional discovery if it could justify the same on a claim-by-claim basis. And, Astra had 30 days after the Court-ordered deposition during which it could have asked the Magistrate for more discovery prior to the date DRL was permitted to make its motion. DRL Ex. 14 ¶ 9. Astra did not go to the Magistrate for additional discovery, and instead chose to pursue a strategy of waiting until after DRL filed its motion and the opposition became due to ask for a continuance. Astra's request for a continuance is simply too late. *See Consorcio Prodipe, S.A. de C.V. v. Vinci, S.A.*, 544 F. Supp. 2d 178, 188 (S.D.N.Y. 2008) (Rule 56(f) request denied when "decision to remain silent on the perceived shortcomings in defendants' pre-motion discovery responses was purely tactical.").

II. The Discovery Astra Seeks Would Be Futile

A. Astra Cannot Prove DRL's ANDA Product Is More Than 70% Crystalline

Astra does not dispute that its product claims require DRL's finished product to contain omeprazole magnesium that is more than 70% crystalline. But Astra's papers do not explain how the requested discovery will show that the material in DRL's finished product will have the required crystallinity. Using the XRPD methodology specified in the claims of Astra's patents, Astra's experts were unable to find omeprazole magnesium crystals in the sample of DRL's finished product that Astra received last September. Astra Br. p.4. Astra explains its failure by asserting that it "may be difficult or impossible" to use the methodology specified by the claims to test DRL's finished product. Luk Decl. ¶ 28. But it is Astra's own patent claims which specify the XRPD method to be used to test for crystallinity. Astra has not identified the "other

methods that might be used to measure crystallinity," and Astra has not explained why the unidentified methods would succeed where the method recited in its claims has failed. *Id.*

DRL's omeprazole magnesium active ingredient is made in an ATFD and its finished product is a formulated tablet where the various drug and coating layers are applied in a fluidized bed apparatus. 2nd Brittain Decl. ¶ 41. Not only have Astra's experts not detected 70% crystallinity in DRL's finished product by the XRPD method specified in the claims, or by any other method, they do not explain based on the process and apparatus that DRL uses to make its finished product why the finished product would be expected to contain omeprazole magnesium that is at least 70% crystalline.

Astra's reliance on the FDA deficiency letter (Astra Br. p.24) is misleading. First, the FDA examiner did not say that he believed the material to be crystalline, but merely questioned whether it might be a hydrated species. Luk Ex. 3 at DRL 02629, ¶ 4. More importantly, the inquiry related to DRL's active drug substance (*i.e.* the active ingredient) and not its finished product. Astra has simply not explained how the requested discovery would allow it to prove infringement of any of its product claims. *See Phillips Petroleum Co. v. Huntsman Polymers Corp.*, 157 F.3d 866, 876 (Fed. Cir. 1988) (conclusory expert declarations devoid of facts upon which the conclusions were reached fail to raise a genuine issue of material fact which would preclude summary judgment); 3rd Brittain Decl. ¶ 13.

Dr. Luk speculates that DRL's product "very possibly" contains highly crystalline omeprazole magnesium. Luk Decl. ¶ 6. And, although unable to opine that DRL's finished product infringes any of the claims, he manages to speculate that "[i]t would make sense for DRL's product to contain highly crystalline omeprazole magnesium" on the ground that omeprazole magnesium that is not highly crystalline is "less attractive in full scale production." Luk Decl. ¶ 5. Dr. Luk's reasoning is faulty. A competitor knowing about Astra patents

claiming highly crystalline omeprazole magnesium would be highly motivated to use amorphous material even if it was less attractive. Moreover, REDACTED REDACTED that does not mean that DRL has trouble using amorphous material in DRL's process. *See* 3rd Brittain Decl. ¶ 12. Indeed, Astra's experts do not even discuss the details of the fluidized bed process that DRL uses to make its finished product, let alone explain why there would be any problem or difficulty using amorphous material in that process. Thus, any opinion that DRL must be using highly crystalline material is unscientific speculation.

Rather than come forward with proof of infringement, which does not exist, Astra attacks the reliability of DRL's test data, all of which shows that DRL's material is non-crystalline to a 1% limit of detection. DRL does not have a burden of proving non-infringement. It is Astra that has the burden of proving that it has evidence that DRL infringes each element of at least one claim. *See Novartis Corp. v. Ben Venue Labs., Inc.*, 271 F.3d 1043, 1046 (Fed. Cir. 2001). Criticizing DRL's non-infringement evidence does not help Astra meet its burden of coming forward with affirmative evidence that DRL infringes any of the claims.

B. DRL's Process Is Beyond the Scope of the Claims

Claim 10 of the '960 patent plainly requires the step of forming a core that contains omeprazole magnesium which is at least 70% crystalline. DRL Ex. 3, claim 10, step (a). Although Astra's lawyer argues that the requested discovery is expected to show that DRL's omeprazole magnesium "is crystalline or highly crystalline during at least part of the manufacturing process" (Griem Aff. ¶ 73, emphasis added), he does not say if he is referring to the manufacture of the finished product or the manufacture of the active ingredient. Astra does not explain how the requested discovery will show that during the manufacture of its finished product DRL forms a core comprising at least 70% crystalline omeprazole magnesium. 3rd Brittain Decl. ¶ 10.

Claim 10 is also not infringed because estoppel limits the claim to a process where the subcoating is applied in the absence of organic solvents, and DRL uses organic solvents. It is a fundamental tenet of patent law that "[t]he patentee is held to what he declares during the prosecution of his patent." *Gillespie v. Dywidag Sys. Int'l, USA*, 501 F.3d 1285, 1291 (Fed. Cir. 2003). Arguments made to distinguish prior art limit the scope of the issued claims. *Id.* Arguments made to distinguish prior art can also create an estoppel that prevents the patentee from using the doctrine of equivalents to recapture in court the subject matter surrendered at the PTO. *PODS, Inc. v. Porta Stor, Inc.*, 484 F.3d 1359, 1368 (Fed. Cir. 2007) (the relevant inquiry is whether a competitor would reasonably believe that the patentee surrendered the relevant subject matter). Here the patentee obtained claim 10 of the '960 patent by arguing that its "novel water-based process" was "environmental-friendly through the absence of organic solvents." DRL Ex. 5 at p.8. Astra attempts to avoid estoppel by arguing that it was trying to persuade the PTO of the novelty of its examples and not the novelty of its claims. Astra Br. p.19 n.6. Review of the file history, however, shows that the argument was made to persuade the PTO of the novelty of Astra's claims. DRL Ex. 5 at p.5 ("the water-based pharmaceutical formulation as presently claimed.") (emphasis added).

Astra does not contest that DRL uses at least some organic solvents to apply its subcoating. A subcoating process that uses organic solvents cannot be the equivalent of a process done in the "absence of organic solvents" because "[t]he opposite of a claim limitation cannot be considered its equivalent." *British Telecomm. PLC v. Prodigy Comm'n Corp.*, 217 F. Supp. 2d 399, 412 (S.D.N.Y. 2002) (McMahon, J.); *see Moore U.S.A., Inc. v. Standard Register Co.*, 229 F.3d 1091, 1106, 1115 n.5 (Fed. Cir. 2000).

Estoppel also limits the claims of the '424 patent. Astra argued to the PTO that the process of the '424 patent was patentable precisely because of the "distinguishing feature" that,

after aqueous alcohol was used "to put omeprazole in solution," the process employed "the use of a different solvent, *i.e.*, water, to recover the crystalline magnesium omeprazole salt from solution." DRL Ex. 8 at p.5 (emphasis added). Astra relied on a declaration to argue that "[t]he use of different solvents as part of the controlled crystallization step" was "an important contribution." *Id.*; DRL Ex. 21 at ¶ 14. Even if it could be shown -- and it has not been shown -- that water in DRL's ATFD contributes to the crystallinity of the omeprazole magnesium that is recovered in the ATFD by the evaporation of organic solvent, there is no evidence that water in the ATFD contributes to the recovery of omeprazole magnesium salt from solution. 3rd Brittain Decl. ¶ 7.

While Dr. Luk speculated that "it is likely that some crystallization is occurring in the ATFD," Luk Decl. ¶ 29, he did not opine that DRL's ATFD process infringed claim 11 or 20 of the '424 patent. He did not dispute that DRL obtains its omeprazole magnesium from the solution in the ATFD by the evaporation of organic solvent. And he did not opine that obtaining solid omeprazole magnesium from solution by removing the organic solvent in the ATFD is the equivalent of using water as a different solvent to recover omeprazole magnesium from solution.

Prosecution history estoppel bars Astra from asserting the doctrine of equivalents with respect to the "by the addition of water" limitation. Astra cannot use the doctrine of equivalents because Astra argued that its process was special because it used water to recover the omeprazole magnesium from solution and also because the doctrine of equivalents is not available with respect to a limitation that was added by amendment to a claim for purposes of patentability. *See Deering Precision Instruments, L.L.C. v. Vector Distrib. Sys., Inc.*, 347 F.3d 1314, 1325-26 (Fed. Cir. 2003).

Amendments that are not "cosmetic" raise a "presumption of prosecution history estoppel." *Id.* at 1326. Here, Astra overcame a rejection, DRL Ex. 22, by amending the claim

that would issue as claim 11 to include the limitation of "by the addition of water," and Astra added the claim that would issue as claim 20 for the explicit purpose of emphasizing the "by the addition of water" limitation, DRL Ex. 23 at pp. 2-4, raising a presumption of estoppel. It is uncontested that Astra amended claims 11 and 20 of the '424 patent, and Astra did not raise any of the exceptions to amendment-based estoppel. On these facts alone, Astra is estopped from asserting the doctrine of equivalents. *Deering*, 347 F. 3d at 1326.

C. Astra Has the ANDA, Which Governs the Infringement Analysis

When a generic company seeks to sell an ANDA product, "the 'ultimate question of infringement is usually straightforward.'" *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1249 (Fed. Cir. 2000) (citation omitted); *see also Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1364 (Fed. Cir. 2003) ("[T]he ANDA must be judged on its face for what an accused infringer seeks the FDA's approval to do. . . . The infringement case is therefore limited to an analysis of whether what the generic drug maker is requesting authorization for in the ANDA would be an act of infringement if performed." (emphasis added)). By producing the requested portions of its ANDA and DMF, 3rd Weinstein Decl. ¶¶ 9-15, DRL gave Astra the operative documents needed to determine whether or not DRL infringes the Astra patents-in-suit.

Astra's assertion that DRL refused to produce a complete copy of its ANDA and DMF is disingenuous at best. Document Request No. 1 only requested the Chemistry, Manufacturing and Controls section. DRL Ex. 25, Request No. 1. The requested section and any related supplements and amendments were produced. 3rd Weinstein Decl. ¶ 14. And Astra only requested the "[p]ortions" of the DMF "relating to properties of DRL's omeprazole magnesium" and all supplements and amendments. DRL Ex. 25, Request No. 2. DRL produced these materials as well. 3rd Weinstein Decl. ¶ 15. Although Document Request No. 2 did not ask for the portion of the DMF that included the description of DRL's process for making its active

ingredient (*see* DRL Ex. 25, Request No. 2), DRL produced these materials in advance of the Court-ordered deposition. 3rd Weinstein Decl. ¶ 13.

Astra's request for additional infringement discovery is déjà vu all over again. The parties and the Court have been down this road before. This case is ripe for summary judgment. Responding on June 25 to Astra's June 23 letter informing the Court that it would not withdraw its case, the Court ordered that "we will proceed to decide the motion to dismiss." DRL Ex. 18.

III. DRL Meets the Evidentiary and Procedural Burdens for Summary Judgment

Astra misstates the law when it says (at 13) that DRL must "fulfill its initial burden of providing admissible evidence of the material facts entitling it to summary judgment . . .," *citing Giannullo v. City of New York*, 322 F.3d 139, 140-41 (2d Cir. 2002) (citation omitted). But where the nonmoving party will bear the burden of proof at trial, as Astra does here, a summary judgment motion "may properly be made in reliance solely on the 'pleadings, depositions, answers to interrogatories, and admissions on file." *Celotex Corp. v. Catrett*, 477 U.S. 317, 324, 106 S. Ct. 2548, 2553 (1986). This means that where the non-moving party bears the burden of proof, the moving party "may use a memorandum or brief to 'point to' the absence of evidence and thereby shift to the nonmovant the obligation to come forward with admissible evidence supporting its claim." *Feurtado v. City of New York*, 337 F. Supp. 2d 593, 599 (S.D.N.Y. 2004) (citations omitted) ("*Giannullo* did not purport to contradict *Celotex's* holding that in fact a movant is not required to provide admissible evidence where the movant does not bear the burden of proof."). Moreover, the cases on which Astra relies (at 14-15) addressed the insufficiencies of the affidavits submitted in efforts to defeat summary judgment.

Astra complains that Dr. Brittain did not rely on the "direct evidence" of DRL's process, *i.e.*, DRL's ANDA and DMF materials. Astra Br. p.14. As he plainly stated in his declaration, Dr. Brittain relied on the detailed description of DRL's process as presented in DRL's response

to AstraZeneca Interrogatory No. 10. 2nd Brittain Decl. ¶ 36. Dr. Brittain should be allowed to rely on the summary description of the process in DRL's sworn response to Interrogatory No. 10 because Astra, who has the corresponding sections from DRL's ANDA and DMF (DRL Exs. 19 and 20), has not argued that DRL's Response to Interrogatory No. 10 is not an accurate summary. *See Nichols v. Upjohn Co.*, 610 F.2d 293, 293-94 (5th Cir. 1980).

Nonetheless, to eliminate any possibility that Dr. Brittain's opinions would have been different if based on DRL's ANDA and DMF, Dr. Brittain has reviewed the materials that Astra said he should have reviewed and his opinions have not changed. 3rd Brittain Decl. ¶¶ 2, 4, 8. Specifically, DRL uses an ATFD to obtain omeprazole magnesium by the evaporation of organic solvent (2nd Brittain Decl. ¶ 50), DRL does not apply the subcoating of its finished drug product in the absence of organic solvents (2nd Brittain Decl. ¶ 53), and DRL uses a fluidized bed process to formulate its finished product (2nd Brittain Decl. ¶ 41).

IV. Claim Construction Does Not Impede Summary Judgment

Astra argues that the need for claim construction makes summary judgment premature. Astra Br. p. 16-17. Astra is wrong. The Court need only construe the claims to the extent needed to determine infringement, and no particular procedure is required. *Ballard Med. Prods. v. Allegiance Healthcare Corp.*, 268 F.3d 1352, 1358 (Fed. Cir. 2001). Any necessary claim construction is a legal issue that can be decided now. Most of the claims plainly require omeprazole magnesium that is at least 70% crystalline. Astra Br. p.19. Moreover, the estoppels relied on by DRL (*i.e.*, the absence of organic solvents in making the finished tablet and the use of water to recover omeprazole magnesium from solution) are based on arguments and amendments made to the PTO which can be ascertained directly from the undisputed record of the prosecution history. Prosecution history estoppel "is a purely legal issue." *Bayer*, 212 F.3d at 1254 ("testimony as to what a reasonable competitor would conclude from the prosecution

history cannot create a genuine issue of material fact so as to bar summary judgment"). Summary judgment is meant to resolve legal issues, such as prosecution history estoppel, where there are no genuine issues of material fact.

V. Conclusion

For the foregoing reasons, Astra has not met its burden of raising a genuine issue of fact concerning infringement and DRL is entitled to summary judgment that it does not infringe United States Patent 5,900,424 or United States Patent 5,690,960.

Dated: August 13, 2008

Respectfully submitted,

s/ Louis H. Weinstein
Louis H. Weinstein
BUDD LARNER, P.C.
150 John F. Kennedy Parkway
Short Hills, NJ 07078
(973) 379-4538 (tel)
(973) 379-7734 (fax)
E-mail: lweinstein@budd-larner.com

Attorneys for Defendants
Dr. Reddy's Laboratories, Ltd. and
Dr. Reddy's Laboratories, Inc.

CERTIFICATE OF SERVICE

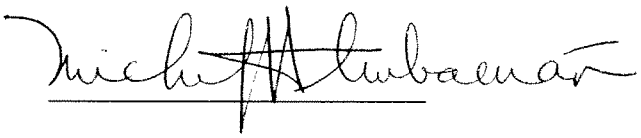
I certify that on this 13th day of August 2008, I caused a true and correct copy of the foregoing:

DRL DEFENDANTS' REPLY
IN SUPPORT OF DRL'S MOTION FOR SUMMARY JUDGMENT

to be served upon counsel for AstraZeneca in the following manner:

By Federal Express

Errol B. Taylor, Esq.
Milbank, Tweed, Hadley & McCloy LLP
1 Chase Manhattan Plaza
New York, New York 10005-1413
Telephone: 212-530-5000
Facsimile: 212-530-5219



687084